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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,765	04/20/2004	James Fink	016770-007100US	5232

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CORPORATE INTELLECTUAL PROPERTY
ONE HEALTH PLAZA 104/3
EAST HANOVER, NJ 07936-1080

EXAMINER	
OSTRUP, CLINTON T	
ART UNIT	PAPER NUMBER
3771	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/828,765	FINK ET AL.	
	Examiner	Art Unit	
	CLINTON OSTRUP	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 February 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-31* is/are rejected.

7)☒ Claim(s) *21 and 24* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is in response to the amendment file February 27, 2008. AS directed by the amendment, claims 20 and 24 have been amended and claim 31 has been added. Thus, claims 20-31 are pending in this application.

Claim Objections

2. Claims 21 & 24 is objected to because of the following informalities: Claim 24 uses the term “vibrating aperture-type” to define the invention; however, it is unclear what is included or excluded by the term “type.”

3. The addition of the word "type" to an otherwise definite expression (e.g., Friedel-Crafts catalyst) extends the scope of the expression so as to render it indefinite. *Ex parte Copenhaver*, 109 USPQ 118 (Bd. App. 1955). Likewise, the phrase "ZSM-5-type aluminosilicate zeolites" was held to be indefinite because it was unclear what "type" was intended to convey. The interpretation was made more difficult by the fact that the zeolites defined in the dependent claims were not within the genus of the type of zeolites defined in the independent claim. *Ex parte Attig*, 7 USPQ2d 1092 (Bd. Pat. App. & Inter. 1986). Appropriate correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 20-31 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

6. The phrase "in close proximity" in claims 1 and 24 is a relative phrase which renders the claims indefinite. The phrase “in close proximity" is not defined by the claims, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear what distance is included or excluded by the claims. How close does the “introducing of an aerosolized medicament into the second gas flow” have to be to be included or excluded from the claim? Likewise, for claim 24, it is unclear how close the “vibrating aperture-type nebulizer coupled to the respiratory circuit” must be to the “patient interface device” to be included or excluded from the claim.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. Claims 20, 29, and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bird US 6,581,600 B2.

As to claim 20, Bird in figure 1 discloses a pressure assisted breathing system having a pressure generating circuit (circuit comprising ventilators 12 and 21, and tubes 78, 88, and 117) and a respiratory circuit (circuit comprising a nebulizer 56 and tube 123 conveying nebulizing fluid). Bird further discloses control knobs 34 and 36, which can be adjusted to control a gas flow though the pressure generating circuit (col.7, lines 65-68,

col.8, and lines 1-18), thus, knobs can be adjusted to provide a first gas flow of sufficiently high volume to maintain continuous positive pressure (CPAP) in the system. In col.7, lines 47-54 Bird also teaches that his system is capable of maintaining a CPAP. Figure 1 of Bird shows that the respiratory circuit (which is shown to be in close proximity to the patient interface device and would avoid dilution f the aerosolized medicament that is delivered to the patient's respiratory system, as compared to the connection being made upstream on tube 78) is separate from a high flow gas line and no additional pressure is maintained at this gas line, thus a second gas flow though tube 123 is inherently lower volume than the first flow. Bird further discloses a patient interface (11/endotracheal tube, see col.4, line 31) being engaged with the patient's respiratory system. Figure 1 of Bird shows a nebulizer (52) is connected to the second gas flow of lower volume, thus, dilution of the aerosolized medicament delivered to the patient's respiratory system is inherently prevented. Although Bird lacks detailed method step as cited in claim 20, however, it would have been obvious to one of ordinary skill in the art to perform the method of respiratory therapy as claimed while using the pressure assisting breathing system of Bird.

As to claims 29 and 30, Bird discloses said interface is an endotracheal tube (see col.4, lines 31).

9. Claims 21-28, 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bird US 6,581,600 B2 in view of Davison GB 2,272,389.

As to claim 21, Bird lacks a vibrating aperture-type aerosol generator for aerosolizing the liquid medicament and a connector for connecting the nebulizer to the

respiratory circuit so as to entrain the aerosolized medicament from the aerosol generator into the gas flowing through the respiratory circuit. However, Davison teaches a vibrating aperture-type aerosol generator (fig.2) for aerosolizing the liquid medicament and a connector (2) for connecting the nebulizer to the respiratory circuit (32) so as to entrain the aerosolized medicament from the aerosol generator into the gas flowing through the respiratory circuit. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have substituted the nebulizer disclosed by Bird with the vibrating aperture-type aerosol generator, as taught by Davison, in order to obtain a vibrating aperture-type aerosol generator that facilitates the dispensing of all of the liquid coming into contact with the rear face of the membrane as a single dose (page 2, lines 10-13).

As to claim 22, Davison teaches the nebulizer comprises a reservoir (14) having a capacity equal to one unit dose of medicament and substantially all of the contents of the reservoir is delivered to the patient's respiratory system without the need to replenish the reservoir (page 2, lines 10-13).

As to claim 23, Davison discloses a reservoir (14) having a variable capacity (fig.2); consequently, it would have been obvious to adjust the volume of the reservoir to any desired volume including 4ml or less.

As to claim 24, Bird discloses a CPAP system, a pressure-generating circuit with a first gas flow of sufficiently high volume to maintain continuous positive airway pressure in the system, a respiratory circuit connected to the pressure generating circuit to a patient interface device as applied for claim 20. Bird teaches a nebulizer (56), which

can be adapted to introduce a liquid surfactant. Bird however lacks a vibrating aperture type nebulizer coupled to the respiratory circuit. However, Davison teaches a vibrating aperture-type aerosol generator (fig.2) for aerosolizing the liquid medicament and a connector (2) for connecting the nebulizer to the respiratory circuit (32) so as to entrain the aerosolized medicament from the aerosol generator into the gas flowing through the respiratory circuit. An advantage of the vibrating aperture-type aerosol generator is that it facilitates the dispensing of all of the liquid coming into contact with the rear face of the membrane as a single dose (page 2, lines 10-13). Riggs discloses whereby the patient breathes the aerosolized surfactant through the patient interface device (col.14, lines 20-38). Although Bird lacks detailed method step as cited in claim 24, however, it would have been obvious to one of ordinary skill in the art to perform the method of respiratory therapy as claimed while using the pressure assisting breathing system of Bird as modified by Davison.

As to claim 25, Bird lacks the surfactant is phospholipids. However, it is known in the art that the surfactant can have variety of composition including phospholipids. Furthermore, it would have been obvious to select a particular composition of surfactant to meet patient's therapy requirement.

As to claims 26 and 28, Bird lacks wherein 6-18% of the aerosolized surfactant is delivered to the patient and wherein the dose is equal to 10 mg or less of surfactant. However, the particular amount of each dose and the particular amount of aerosolized medicament that is delivered to a patient can be arrived at through mere routine obvious experimentation and observation with no criticality seen in any particular amount

including 6-18% and 10mg or less. Furthermore, the particular amount and concentration of medicament is dependent upon the particular medical needs of a patient and is adjusted accordingly.

As to claim 27, Bird lacks the entire dose is delivered to the patient and the dose is equal to 10 mg or less of surfactant. However, Davison teaches the nebulizer comprises a reservoir (14) having a capacity equal to one unit dose of medicament and substantially all of the contents of the reservoir is delivered to the patient's respiratory system without the need to replenish the reservoir (page 2, lines 10-13). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify Bird in order to provide the dosing capacity as claimed for the purposes of delivering contents of medicament without the need to replenish the reservoir as taught by Davison.

Regarding claim 31, Davison teaches the nebulizer comprises a reservoir (14) having a capacity equal to one unit dose of medicament and substantially all of the contents of the reservoir is delivered to the patient's respiratory system without the need to replenish the reservoir (page 2, lines 10-13); therefore teaching a volume of medicament delivered being sufficient for one treatment..

Response to Arguments

10. Applicant's arguments filed 2/27/08 have been fully considered but they are not persuasive. Applicant argues Bird teaches away from the placement of the nebulizer near to the patient and that Bird teaches a single closed circuit not separate pressure and respiratory circuits.

The nebulizer (56) of Bird is "in close proximity to the patient interface device" as claimed. See: Figure 1. Regarding the pressure generating circuit and respiratory circuit claimed, Bird clearly describes a high-volume ventilator (16) for the first circuit (78) and a second percussive ventilator (21) which is connected to the nebulizer and tube (123) forming the respiratory circuit. Thus, Bird discloses two circuits, with one circuit having a higher volume flow than the other. See: col. 4, lines 8-13 & 27-65.

Applicant's argument that Davidson is limited to describing a self-contained apparatus, which has utility for inhalation therapy and cannot teach utilizing the aerosolization apparatus in a pressure-assisted breathing system, has not been taken well because the rejection was based on a combination of references and Bird was used to teach the ventilation circuit. Davidson was merely used to teach the obviousness of utilizing a vibration aperture-type aerosol generating device in the system disclosed by Bird. Thus, Bird discloses a nebulizer in a pressure-assisted breathing system and Davidson teaches the specific type of aerosol generator claimed.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have substituted the nebulizer disclosed by Bird with the vibrating aperture-type aerosol generator, as taught by Davison, in order to obtain a vibrating aperture-type aerosol generator that facilitates the dispensing of all of the liquid coming into contact with the rear face of the membrane as a single dose (page 2, lines 10-13 of Davidson).

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies

(i.e., the step of introducing aerosolized medicament into a location outside the high-volume gas flow in the pressure-generating circuit, such as the respiratory circuit, thereby avoiding dilution of the aerosolized medicament and increasing the amount of aerosolized medicament delivered to the patient's respiratory system) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). .

Moreover, the claims do not require the pressure-generating circuit and respiratory circuit be separately and individually coupled to a patient interface device, as the pressure-generating circuit is merely “adapted to be coupled to a patient interface.” It has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138. Given that the system of Bird is disclosed as being attached to a patient interface, including an endotracheal tube, it is clearly “adapted to be coupled to a patient interface” as claimed.

Therefore, the said rejections have been MAINTAINED.

Conclusion

11. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Tsukashima et al. (7,101,341); Tsukashima et al. (2004/0210153); Haveri (6,539,937); Alston et al., (2005/0139211); Heinonen (6,530,370); Power (6,615,824); which are all drawn to ventilation systems with nebulizers.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

13. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CLINTON OSTRUP whose telephone number is (571)272-5559. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Clinton Ostrup/
Examiner, Art Unit 3771

/Justine R Yu/
Supervisory Patent Examiner, Art Unit 3771